JAN - 5 2001

K003292
Page 1 of 3

510(k) Summary
260 Corvus
Pie Medical

510(k) Summary

The following safety and effectiveness summary has been prepared pursuant to requirement for 510(k) summaries specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Colleen Hittle, Official Correspondent
8000 Castleway Drive
Indianapolis, IN 46250
Phone: (317) 849-1916
Facsimile: (317) 5779070

Contact Person: Colleen Hittle

Date: October 18, 2000

807.92(a)(2)

Trade Name:	260 Corvus Ultrasound Imaging Systems	
Common Name:	Ultrasound Imaging System	
Classification Name(s):	Ultrasonic pulsed doppler imaging system	892.1550
	Ultrasonic pulsed echo imaging system	892.1560
Classification Number:	90IYO	

807.92(a)(3)

Predicate Device(s)

Pie Medical	250	K915647

Additional Substantial Equivalence Information is provided in the following substantial Equivalence Comparison Table.

510(k) Summary
260 Corvus
Pie Medical

807.92(a)(5)

Device Description

Intended Use(s)

Pie Medical's 260 Corvus ultrasound systems used are to perform general diagnostic ultrasound studies under a physician's supervision including: abdominal, small organ, fetal, pediatric, peripheral vascular, intraoperative abdominal, musculoskeletal, cardiac, transrectal and transvaginal.

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Page 3 of 3

510(k) Summary
260 Corvus
Pie Medical

Comparison Chart for Substantial Equivalence

	PIE 1150 (Predicate to 250, cleared via K900469)	**PIE 250 (Predicate to 240, cleared via K915647**	**PIE 260Corvus To be added with this submission**
Technology	Linear/Curved/ Mechanical Annular	Annular	Annular/Curved/Linear
Modes	B, B+M, M	B, B+B. B+M, M	B, B+B, B+M, M
Frequencies	3.5 – 7.5 MHz	3.5-7.5 MHz	3.5-8MHz
Applications	Abdominal/Fetal/ Pediatric/ Small organ/ Intraoperative	Abdominal / Small Organ/ Intraoperative/ Pediatric/ Peripheral Vascular/ Fetal	Abdominal/Small Organ/ Transvaginal/ Transrectal/ Intraoperative/Neonatal Cephalic/Pediatric/ Peripheral Vascular/ Fetal/Cardiac/ Musculoskeletal
Scan Converter	Full digital	Full digital	Full digital

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 2001

Pie Medical
c/o Ms. Colleen Hittle
Official Correspondent
The Anson Group
7992 Castleway Drive
Indianapolis, Indiana 46250

Re: K003292
260 Corvus Ultrasound Imaging Systems
Dated: October 18, 2000
Received: October 20, 2000
Regulatory Class: II
21CFR §892.1560/Procode: 90 IYO
21CFR §892.1570/Procode: 90 ITX

Dear Ms. Hittle:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 260 Corvus Ultrasound Imaging Systems, as described in your premarket notification:

Transducer Model Number

401669 3.5/5.0 MHz Linear Array
410054 6.0/8.0 MHz Linear Array
402198 8.0 MHz Linear Array
401664 3.5/5.0 MHz Curved Array
401667 5.0/7.5 MHz Curved Array
401788 5.0/7.5 MHz Curved Array
402116 3.5/5.0 MHz Curved Array
402155 5.0/7.5 MHz Annular Array
402154 5.0/7.5 MHz Annular Array
402156 5.0/7.5 MHz Annular Array
402143 3.5 MHz Annular Array
402157 5.0/7.5 MHz Annular Array

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Paul M. Gammell, Ph.D. at (301) 594-1212.

Sincerely yours,

for Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

260 Corvus System

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac		N	N						N	
Tranesophageal										
Transrectal		N	N						N	
Transvaginal		N	N						N	
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

N= new indication: P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Small Organs (specifically, thyroid, testicles, and breast)

Applicable combined modes: B+B; B+M

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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Additional Comments:

Applicable combined modes: B+B; B+M

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

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Ophthalmic										
Fetal										
Abdominal		N	N						N	
Intraoperative Adominal		N	N						N	
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

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David G. Hyman

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

260 Corvus - #402198

Appendix F

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

	Mode of Operation									
Clinical Application	A	B	M	PWD	CWD	Color Doppler CFM	Amplitude Doppler PD	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Tranesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional		N	N						N	
Musculo-skeletal Superficial		N	N						N	
Other										

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Applicable combined modes:

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

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Ophthalmic										
Fetal		N	N						N	
Abdominal		N	N						N	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)										
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Cardiac										
Tranesophageal										
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Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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Additional Comments:

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Prescription Use ✓
(Per 21 CFR 801.109)

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Ophthalmic										
Fetal										
Abdominal		N	N						N	
Intraoperative Abdominal		N	N						N	
Intraoperative Neurological										
Pediatric		N	N						N	
Small Organ (specify)		N	N						N	
Neonatal Cephalic		N	N						N	
Adult Cephalic										
Cardiac										
Tranesophageal										
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Transurethral										
Intravascular										
Peripheral Vascular		N	N						N	
Laparoscopic										
Musculo-skeletal Conventional										
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Other										

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Applicable combined modes: B+B; B+M

David C. Hegarty

(Division Sign-Off)

Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Per 21 CFR 801.109)

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Applicable combined modes: B+B; B+M

David A. Clegorn

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

510(k) Number K003292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

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Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other										

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Additional Comments:

Combined Mode: B + M

David C. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K003292

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
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Applicable combined modes: B+B; B+M

David A. Bergman

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

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Prescription Use ✓
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Diagnostic Ultrasound Indications for Use Form

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David C. Lagnon

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices

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Prescription Use ✓
(Per 21 CFR 801.109)

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David A. Hyman
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David A. Lehmann

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Division of Reproductive, Abdominal, ENT, and Radiological Devices

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David A. Lazorn
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(Per 21 CFR 801.109)